Glyphosate

Interim Registration Review Decision
Case Number 0178

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Approved by: _____
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I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) *Interim Registration Review Decision* (ID) for glyphosate acid (PC Code 417300) and its various salt forms (PC Codes 103601, 103604, 103605, 103607, 103608, and 103613; case 0178), and is being issued pursuant to 40 CFR § 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an Interim Registration Review Decision before completing registration review. Among other things, the Interim Registration Review Decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review case. Additional information on glyphosate can be found in the EPA's public docket (EPA-HQ-OPP-2009-0361) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing an ID for glyphosate so that it can (1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation (see Appendices A and B). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, the Services) to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although the EPA has not yet fully evaluated risks to federally-listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for glyphosate prior to completing the glyphosate registration review. Likewise, the agency will complete endocrine screening for glyphosate, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices D and E, respectively, for additional information on the listed species assessment and the endocrine screening for the glyphosate registration review.

In addition, in September 2018, the Environmental Working Group (EWG) along with several other stakeholders, collectively referred to as EWG et al. hereafter, petitioned the agency to

reduce the glyphosate tolerance in oats to 0.1 parts per million (ppm) and to require labels for registered glyphosate products to explicitly prohibit the use of glyphosate as a preharvest desiccant. The agency is in the process of reviewing comments submitted on the 2018 EWG et al. petition and responding to the EWG et al. petition; to the extent the issues in the petition impact the registration review case, EPA will incorporate its responses to the petition into its final registration review decision for glyphosate. To view the EWG et al. petition and related documents, visit docket ID: EPA-HQ-OPP-2019-0066 at regulations.gov.

The glyphosate registration review case covers glyphosate acid (PC code 417300) and the following salt forms with active pesticide registrations: isopropylamine salt (PC code 103601), ammonium salt (PC code 103604), ethanol amine salt (PC code 103605), diammonium salt (PC code 103607), dimethyl ammonium salt (PC code 103608), and the potassium salt (PC code 103613). Glyphosate is a non-selective, systemic herbicide with products registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, cereal grains, and other field crops. Non-agricultural uses include residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land. Glyphosate products are also registered for use on the glyphosate-resistant crops, including alfalfa, corn, soybean, cotton, canola, and sugar beets. The first pesticide product containing glyphosate was registered in 1974; a Reregistration Eligibility Decision (RED) for glyphosate was completed in 1993. Since then, the EPA has reviewed the risk assessments for glyphosate to determine if updates were necessary when new uses were added to glyphosate labels.

This document describes any changes since the Proposed Interim Registration Review Decision (PID), includes a summary of public comments on the PID, and includes the agency's interim registration review decision and the agency's rationale. See the PID for a summary of glyphosate's registration review timeline, use and usage information describing how and why glyphosate is used, the EPA's risk and benefits assessments, and a discussion of risk characterization. The PID also describes the mitigation measures that were proposed to address risks of concern and the regulatory rationale for the EPA's proposed interim registration review decision.

A. Updates Since the Proposed Interim Registration Review Decision was Issued

In April 2019, the EPA published the PID for glyphosate. Since that time, the agency has reviewed public comments and has made changes to the spray drift management labeling and rotational crop timing language that was proposed in the PID. The changes for spray drift management labeling are as follows: changes in droplet size restrictions, the removal of advisory spray drift statements for airblast applications, and the incorporation of updated swath displacement language for aerial applications. In addition, the agency has updated the language regarding rotational crop timing to provide clearer directions for use. For more information on the changes made to the mitigation proposed in the PID, please refer to Section IV.A. and Appendix A. There have been no additional updates to what was proposed in the PID, nor any updates to the draft risk assessments (DRAs). This document thus finalizes the agency's draft supporting documents *Glyphosate Draft Human Health Risk Assessment for Registration Review* and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*,

which are available in the public docket. Along with the ID, the following documents are also posted to the glyphosate docket:

- *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision*, dated January 16, 2019
- *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, dated January 13, 2019

B. Summary of Public Comments on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period for the PID, which opened on May 6, 2019, the agency received comments requesting an extension of the public comment period from the original deadline of July 5, 2019. The agency extended the comment period for 60 days, which then closed on September 3, 2019. During the 120-day comment period, the agency received roughly 283,300 comments. Over 12,000 unique submissions were received from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, the U.S. Department of Agriculture and members of the general public. Most comments came from mass mailer campaigns, and approximately 120 unique substantive comments were received from various stakeholders.

Along with the ID, the agency is posting the following documents that address comments received on the PID: *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* and *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*. Most of the comments received on the PID are substantively the same as comments received during previous glyphosate comment periods on the agency's risk assessments. The *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment* responds to comments that have not been addressed previously via the December 2016 FIFRA Scientific Advisory Panel (SAP) meeting to discuss the carcinogenic potential of glyphosate[1] or in previous registration review documents for glyphosate. These comments did not result in changes to the agency's risk assessments.

EPA's *Response from the Pesticide Re-evaluation Division to Comments on the Glyphosate Proposed Interim Decision* document combined comments by topic instead of responding to individual stakeholders and directs the public to responses previously provided in EPA documents. Comments specific to the glyphosate mitigation, comments of a broader regulatory nature, and the agency's responses to those comments are summarized below, and some resulted in changes to the mitigation proposed in the PID.

For more detailed responses to comments relating to the human health risk assessment, and EPA's cancer evaluation for glyphosate, see the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* and *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*. For more detailed responses to

[1] Materials from the December 13-16, 2016 FIFRA SAP are posted in docket EPA-HQ-OPP-2016-0385. The final report, the transcript, charge questions, and other materials are also available online: https://www.epa.gov/sap/meeting-materials-december-13-16-2016-scientific-advisory-panel

comments relating to the ecological risk assessment, see the *Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate*. For detailed responses to comments on the use/usage of glyphosate and the benefits, see the *Glyphosate: Response to Comments, Usage, and Benefits (PC Codes: 103601, 103604, 103605, 103607, 103613, 417300)*. All response to comments documents are available in the public docket for glyphosate (EPA-HQ-OPP-2009-0361) and published online[2]. The agency thanks all commenters for their comments and has considered them in developing this ID.

Comments Regarding the Environmental Working Group (EWG) Petition

Comment: On September 27, 2018, the agency received a petition from the Environmental Working Group, Ben & Jerry's Homemade, Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co+op Grocers, Nature's Path Foods Inc., One Degree Organic Foods USA, Inc., and Stonyfield Farms, Inc (EWG et al.). The petitioners requested that the agency reduce the tolerance of the pesticide glyphosate in or on oats from 30 ppm to 0.1 ppm and modify labels to explicitly prohibit preharvest use on oats. The petitioners asserted that the current tolerance level for oats is not protective enough when assessing people's dietary exposure to glyphosate in oats and the potential carcinogenicity of glyphosate. Numerous members of the general public commented in support of the EWG et al. petition. Various stakeholders and numerous farmers commented in opposition of the petition. EWG et al. also provided comments on the PID that were similar in nature to the issues raised in the petition.

EPA Response: In accordance with FFDCA section 408(d)(3), EPA published EWG et al.'s petition for a 30-day public comment period on May 6, 2019; the public comment period closed on June 5, 2019. The full petition is posted in docket EPA-HQ-OPP-2019-0066 at www.regulations.gov. The agency is still reviewing the 103,447 comments that were received on the petition. This Interim Decision reflects the conclusions of EPA's most recent risk assessments and does not address the claims raised in the petition, or constitute EPA's response to the petition. The agency anticipates issuing the response to the petition in 2020.

Comments Regarding the Human Health Risk Assessment

Comment: The agency received comments regarding the human health risk assessment from a wide array of stakeholders. Topics included concerns with the cancer assessment, toxicological studies, protection of children, and detections of glyphosate. Additionally, open literature studies were also identified for the agency's consideration.

EPA Response: Comments received regarding the human health risk assessment for glyphosate have been previously addressed in the *Glyphosate: Response to Comments on the Human Health Draft Risk Assessment* (EPA-HQ-OPP-2009-0361-2343). Many of the open literature studies were previously identified and considered by the agency as part of two open literature searches. The remaining studies identified during the public comment period were primarily journal articles published since these searches were conducted. None of the open literature

[2] https://www.epa.gov/ingredients-used-pesticide-products/proposed-interim-registration-review-decision-and-responses-0

studies identified for the agency's consideration were found to have an impact on the glyphosate hazard characterization, cancer assessment, or human health risk assessment. The agency will continue to monitor the open literature for studies that use scientifically sound and appropriate methodology and relevant routes of exposure that have the potential to impact the risk evaluation of glyphosate. For more information, please see the *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, which is available on the public docket.

Comments Regarding Spray Drift Management

Comment: Several stakeholders, including USDA and NAAA, provided comments on the proposed droplet size requirement of "fine or coarser," suggesting that a larger droplet size may be more appropriate for glyphosate products where glyphosate is the only active ingredient. The commenters expressed concern that using a fine droplet size might increase the risk of drift while providing no improvement on efficacy, due to the fact that glyphosate is a systemic herbicide that needs less coverage than contact pesticides. Commenters also noted that glyphosate is often tank-mixed with other pesticides and that fine droplet size may be appropriate in those cases to allow greater flexibility for tank mixing.

EPA Response: The agency is requiring label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all products containing glyphosate. The agency's goal is to manage off-target spray drift from application of glyphosate while continuing to preserve glyphosate's utility for growers and allow growers continued flexibility when making applications. Since glyphosate is a systemic herbicide, the agency agrees that "medium" or coarser droplet size is appropriate when glyphosate is sprayed as the sole active ingredient, or when tank-mixed with other systemic herbicides. Since glyphosate is a compound that is frequently tank-mixed with other pesticides (*e.g.* when used with an insecticide in a burndown treatment), the agency agrees that a "fine" droplet size is appropriate when tank-mixing with a pesticide product that requires a fine droplet size. The agency is revising the droplet size labeling based on the comments received. Refer to Section IV.A.1. and Appendix B of this Interim Decision for additional information on the required droplet size language.

Comment: Commenters noted that it is not appropriate to require enforceable spray drift management language for airblast applications, given that herbicides are not applied via airblast to orchards and vineyards.

EPA Response: The agency agrees that airblast application is not an approved application method for glyphosate and has removed this language from the required labeling in Appendix B.

Comments Regarding Rotational Crop Timing

Comment: The Joint Glyphosate Task Force (JGTF), consisting of 26 member companies, commented on the proposed labeling changes for rotational crop timing, suggesting language that provides clearer directions for use.

EPA Response: The agency thanks the JGTF for their comment. The agency has reviewed the suggested language and agrees that the language is more informative and clarifies the directions for use regarding rotational crop timing. Updated label clarification language for rotational crop timing has been included in Appendix B.

Comments Regarding the JGTF "Glyphosate Master Reference Label"

Comment: The JGTF submitted to the agency a document titled "Glyphosate Master Reference Label," which is intended to be used by registrants to aid in the creation and review of product labels containing glyphosate. The "Glyphosate Master Reference Label" intends to define key elements of a glyphosate end-use product label, including precautionary and other label statements, approved crop and non-crop uses, maximum application rates, methods of application, and application restrictions for specific uses.

EPA Response: The agency appreciates the registrant collaboration in identifying currently registered uses of glyphosate in the JGTF's "Glyphosate Master Reference Label". The task force developed this tool as a reference for registrants. While the JGTF's "Glyphosate Master Reference Label" may be used by registrants to aid in label submission, EPA emphasizes that the existing EPA process for reviewing labels as part of registration review still applies.

II. USE AND USAGE

Glyphosate is a broad-spectrum, systemic glycine herbicide which inhibits the enzyme 5-enolypyruvylshikimate-3-phosphate (EPSP) synthase in plants and inhibits aromatic amino acid synthesis. It is the only herbicide in the Weed Science Society of America's (WSSA) group 9 class and it has a unique mode of action. Glyphosate products are registered as ready-to-use solution, water-dispersible granules, soluble concentrate, emulsifiable concentrate, flowable concentrate, water soluble packaging, pressurized liquid, pellets/tablets, and tree injection shells. It can be applied as a pre-emergent, post-emergent, or as a pre-harvest application to the crop to treat a variety of emerged grass and broadleaf weeds. In a few crops (*e.g.* sugarcane), glyphosate is used as a plant growth regulator.

Glyphosate products are registered for use in a wide array of both agricultural and non-agricultural settings. Agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, legumes, cereal grains, and other field crops. Glyphosate products are also registered for use on the following glyphosate-resistant (transgenic) crops: corn, soybean, cotton, canola, sugar beets, and alfalfa. Registered non-agricultural uses include: tree injections, residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land.

Application methods vary for glyphosate and include aircraft, various ground equipment, and various handheld equipment. Application types include: aerial spray, ground boom spray, strip treatment, band treatment, broadcast spray, spot treatment, stump treatment, tree injection, and wipe-on/wiper treatments. The maximum single application rate on labels is up to 8 pounds acid equivalent per acre (lb ae/A) (acid equivalents or ae are used to assess the different acid and salt forms of glyphosate) for the following uses: pastures, non-food tree crops, forestry, aquatic

areas, and non-crop. However, for agricultural row crop uses, maximum single application rates are 1.55 lb ae/A for aerial applications and 3.75 lb ae/A for ground applications. Maximum annual application rates are generally 6 to 8 lbs ae/A, except for residential spot treatments.

The EPA completed a usage analysis for glyphosate by analyzing agricultural market research data from 2012 to 2016. Approximately 281 million pounds of glyphosate was applied to 298 million acres annually in agricultural settings, on average. Most glyphosate was applied to soybean (117.4 million lbs applied annually), corn (94.9 million lbs applied annually), and cotton (20 million lbs applied annually). Many citrus fruits (*e.g.*, grapefruit, oranges, lemons), field crops (*e.g.*, soybean, corn, cotton), and tree nuts (*e.g.*, almonds, walnuts, pistachios) have the highest percentage of their acres treated with glyphosate.

Approximately 24 million pounds of glyphosate are applied to non-agricultural sites annually, on average. The majority of non-agricultural use is in the homeowner market (5 million lbs applied annually), turf (4.9 million lbs applied annually), forestry (3.6 million lbs applied annually), and roadways (3.3 million lbs applied annually).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment was presented in the glyphosate PID. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate. The EPA thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern.

Both non-cancer and cancer effects were evaluated for glyphosate and its metabolites, aminomethyl phosphonic acid (AMPA) and N-acetyl-glyphosate. The human health risk assessment for glyphosate and supporting documents, including the agency's revised issue paper on the carcinogenic potential of glyphosate, are published in the public registration review docket for glyphosate (EPA-HQ-OPP-2009-0361) at www.regulations.gov. The deliberations of the glyphosate FIFRA SAP meeting on the carcinogenic potential of glyphosate, including the agenda, meeting notes, SAP recommendations, the EPA's presentation to the FIFRA SAP, and other supporting documents are published in the glyphosate FIFRA SAP docket (EPA-HQ-OPP-2016-0385) at www.regulations.gov.

The agency concluded that there are no dietary risks of concern for any segment of the population, even with the most conservative assumptions applied in its assessments (*e.g.*, tolerance-level residues, direct application to water, and 100% crop treated). The agency also concluded that there are no residential, non-occupational bystander, aggregate, or occupational risks of concern.

The EPA has not made a common mechanism of toxicity to humans finding as to glyphosate and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, it was not appropriate for EPA to assess cumulative risks.

For additional details on the human health assessment for glyphosate, see the *Glyphosate Draft Human Health Risk Assessment for Registration Review*, which is available in the public docket.

1. Human Incidents and Epidemiological Analysis

The EPA conducted human health incident reviews for glyphosate in February 2014 and in October 2018. Thousands of glyphosate incidents were reported but most reported incidents were minor in severity. The high number of reported incidents across the databases is likely a result of glyphosate being among the most widely-used pesticides in the United States by volume. Health effects reported in the incident databases included dermal, ocular, and respiratory symptoms and effects were generally mild and resolved rapidly. While the agency recently received information regarding litigation related to glyphosate human health incident claims, submitted under the FIFRA 6(a)2 adverse event reporting requirement, the agency does not comment on private litigation. EPA has thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans. The agency will continue to monitor incident information and additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

The medical-case literature was reviewed, and most accidental ingestion of glyphosate formulations result in mild symptoms. Intentional ingestions caused moderate to severe symptoms and involved multiple organ systems.

The epidemiological literature was also reviewed but most studies were hypothesis-generating in nature. The EPA found there was insufficient evidence to conclude that glyphosate plays a role in any human diseases. Since the last EPA review of the epidemiological literature, two studies regarding the association between glyphosate exposure and non-Hodgkin's Lymphoma (NHL) were identified for detailed review by the agency; however, these studies did not impact the agency's assessment. For more information, refer to *Glyphosate: Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment*, which is available on the public docket.

For more information on reported human incidents, see the *Glyphosate: Tier II Incident Report*, available in the in the public docket for glyphosate.

2. Tolerances

Tolerances are established for residues of glyphosate in/on numerous plant commodities in 40 CFR § 180.364. Glyphosate tolerances range from 0.2 to 400 ppm. The EPA evaluated the glyphosate residue chemistry database to determine if the established tolerances conform to current practices and to determine whether updates were necessary for current crop group/subgroup definitions. The EPA intends to establish new tolerances for various vegetable and fruit groups and subgroups, as listed in Table 1. Upon establishment of these new crop group tolerances, EPA intends to remove the following individual tolerances, since they will no longer be needed: acerola; aloe vera; ambarella; asparagus; atemoya; avocado; bamboo, shoots; banana; biriba; breadfruit; cactus, fruit; cactus, pads; canistel; cherimoya; custard apple; date, dried fruit;

durian; feijoa; fig; fruit, stone, group 12; guava; ilama; imbe; imbu; jaboticaba; jackfruit; longan; lychee; mamey apple; mango; mangosteen; marmaladebox; noni; nut, tree, group 14; olive; palm heart; papaya; papaya, mountain; passionfruit; pawpaw; persimmon; pineapple; pistachio; pomegranate; pulasan; rambutan; rose apple; sapodilla; sapote, black; sapote, mamey; sapote, white; soursop; Spanish lime; star apple; starfruit; sugar apple; Surinam cherry; tamarind; vegetable, leafy, brassica, group 5; vegetable, leafy, except brassica, group 4; watercress, upland; and wax jambu. Additionally, EPA is requiring eliminating trailing zeros listed in tolerances consistent with agency policy.

Table 1. Required Changes to the Tolerance Levels or Commodity Definitions for Glyphosate.

Current		Required Change		Comment
Commodity	Tolerance (ppm)	Commodity	Tolerance (ppm)	
Soybean, forage	100.0	Soybean, forage	100	Correct number of significant figures to be consistent with EPA policy
Soybean, hay	200.0	Soybean, hay	200	
Soybean, hulls	120.0	Soybean, hulls	120	
Soybean, seed	20.0	Soybean, seed	20	
Fruit, stone, group 12	0.2	Fruit, stone, group 12-12	0.2	Update to the current crop group definitions; coconut was excluded from the tree nut crop group tolerances as the residues were not within 5x (coconut tolerance at 0.1 ppm)
Nut, tree, group 14	1.0	Nut, tree, group 14-12 (except coconut)	1.0	
Vegetable, leafy, except brassica, group 4	0.2	Vegetable, leafy, group 4-16	0.2	Update to the current crop group definitions
Vegetable, leafy, brassica, group 5	0.2	Vegetable, *Brassica*, head and stem, group 5-16	0.2	
Several	0.2-0.5--	Vegetable, stalk and stem, subgroup 22A	0.5	
	0.2	Vegetable, leaf petiole, subgroup 22B	0.2	
	0.2	Fruit, tropical and subtropical, edible peel, group 23	0.2	
	0.2	Fruit, tropical and subtropical, small fruit, inedible peel, group 24A	0.2	
	0.2	Fruit, tropical and subtropical, medium to large fruit, smooth, inedible peel, group 24B	0.2	
	0.2	Fruit, tropical and subtropical, large fruit, rough or hairy, inedible peel, group 24C	0.2	
	0.2	Fruit, tropical and subtropical, vine, inedible peel, group 24E	0.2	

In accordance with FFDCA, the agency will be conducting rulemaking to implement any tolerance changes identified for glyphosate.

As noted in the PID, the agency received a September 27, 2018 petition from the Environmental Working Group et al., requesting that the agency reduce the tolerance of the pesticide glyphosate in or on oats and modify labels to explicitly prohibit preharvest use on oats. The agency issued a Federal Register Notice of Filing for public comment in a separate docket, EPA-HQ-OPP-2019-0066. This Interim Decision reflects the conclusions of EPA's most recent risk assessments and

does not address the claims raised in the petition or provide EPA's response to the petition. The agency anticipates issuing the response to the petition in 2020.

3. Human Health Data Needs

No additional human health data needs have been identified for the glyphosate registration review beyond the human health data required as part of the registration review DCI, which has been satisfied.

B. Ecological Risks

A summary of the agency's ecological risk assessment was presented in the PID. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of glyphosate.

The agency did not identify potential risks of concern for fish, aquatic invertebrates, or aquatic-phase amphibians. Low or limited potential risks of concern were identified for mammals and birds. Consistent with its mode of action as an herbicide, potential risks to non-target terrestrial and aquatic plants were primarily from spray drift and the resulting distances from the edge of the field to below toxicity threshold were heavily dependent on the application rate used. Given its importance as a critical food resource for the monarch butterfly, the agency also completed a spray drift analysis for common milkweed, with those results being similar to distances calculated for other terrestrial plants tested in ecotoxicity tests (*i.e.*, cucumber).

Based on an adult honey bee acute contact and oral toxicity tests, the likelihood of acute adverse effects to adult bees is considered low at application rates up to 5.7 lb a.e./A; however, it is uncertain if effects would occur at higher application rates (i.e., up to 8 lb a.e./A). In a colony-level study, no adverse effects (acute or sublethal) were reported based on exposure to residues from an application at a rate of 1.92 lb ae/A. However, the full suite of Tier I toxicity studies are unavailable to fully assess potential risk to bees at the individual and/or colony level.

The agency believes that additional data may be necessary to fully evaluate risks to bees. Although the agency did not identify the need for these additional data to evaluate potential effects to bees when initially scoping the registration review for glyphosate, the Problem Formulation and registration review generic data call-in (GDCI) for glyphosate were both issued prior to publication of the June 2014 harmonized *Guidance for Assessing Pesticide Risks to Bees*[3]. This 2014 guidance lists additional laboratory-based studies of individual bees and based on the results of those studies, possible colony-level studies, that were not included in the glyphosate registration review GDCI. Therefore, the agency is currently determining whether additional bee toxicity and exposure data are needed for glyphosate. If the agency determines that additional data are necessary to help make a final registration review decision for glyphosate, then EPA will issue a GDCI to obtain these data. The pollinator studies that could be required for glyphosate are listed in Table 2.

[3] http://www2.epa.gov/sites/production/files/201406/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Table 2: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline (OECD 245)	Honey bee adult chronic oral toxicity
Non-Guideline OECD 239)	Honey bee larvae chronic oral toxicity
Tier 2[†]	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3[†]	
850.3040	Full-Field testing for pollinators

[†] The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its endangered species assessment for glyphosate. The draft biological evaluation for glyphosate is anticipated in 2020.

The agency conducted a review of ecological incidents and determined the majority of the glyphosate incidents are for terrestrial plants. Most plant incidents involved spray drift onto adjacent agricultural crops and grass. Fewer incidents were reported for terrestrial and aquatic wildlife.

For additional details on the ecological assessment for glyphosate, see the *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts*, which is available in the public docket.

1. Ecological and Environmental Fate Data Needs

The ecological effects data required as part of the glyphosate registration review DCI were received and found to be adequate for risk assessment. The agency will issue a DCI for additional pollinator data as part of a separate action if it determines that additional pollinator data are necessary to help make a final registration review decision for glyphosate.

C. Benefits Assessment

Glyphosate is the most commonly used agricultural herbicide in the United States. It is a broad-spectrum herbicide that provides postemergence control of broadleaf, sedge, and grass weeds with minimal residual toxicity to crops or non-target vegetation. Glyphosate is a unique herbicide as it is the only herbicide classified as a Group 9 herbicide by the WSSA, which acts by inhibiting the enzyme EDSP synthase in plants and inhibiting aromatic amino acid synthesis.

Glyphosate is a relatively inexpensive herbicide to apply in agricultural situations, with the cost of applications to most crops ranging $1 to $13 per acre.

Glyphosate products are registered for use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial, and residential areas. Current glyphosate-resistant field crops are soybean, corn, cotton, canola, alfalfa, and sugar beet. Many of these crops, such as corn, cotton, soybean, and sugar beet, have exceptionally high percentages of their acreage treated with glyphosate (approximately 90 percent of acres treated in each crop). Genetically-engineered (transgenic) glyphosate-resistant (GR) varieties of these crops can be sprayed over-the-top with minimal or no crop phytotoxicity, and glyphosate may also be used as a pre-plant burndown in many of these crops. On average, 84 percent of glyphosate applied in agricultural settings, in terms of pounds, is applied to soybeans, corn, or cotton per year.

Glyphosate is also beneficial as part of weed control programs in orchards and specialty crops. Glyphosate use is prevalent in orchards and vineyards, and most acres of crops such as tree nuts, citrus, and grapes are treated with glyphosate. Glyphosate is the most versatile herbicide in orchard floor management because it may be used for under tree weed control, chemical wiping, chemical mowing, and spot treatment. Since glyphosate controls a broad spectrum of weeds and does not have residual soil activity, it can be used to control emerged weeds prior to planting high value crops such as fruits and vegetables, for which growers sometimes have limited weed control options.

Glyphosate is also important for noxious and invasive weed control in aquatic systems, pastures/rangelands, public lands, forestry, and rights-of-way. Invasive weeds controlled by glyphosate include cattails and water hyacinth, which can impede water flow and irrigation. Improper weed management can cause water to stagnate, providing a breeding habitat for mosquitos. Therefore, effective weed control is important for controlling mosquito-borne diseases. Glyphosate is also important for habitat restoration efforts. It is used to control invasive annual, perennial, and woody plants in riparian habitats and rangeland. Glyphosate use in rights-of-way helps keep roadways and railroad tracks safe by protecting the stability of the surface, maintaining visibility for operators, and allowing for the distribution of goods, services, and utilities (gas and electric). Glyphosate is the most frequently used active ingredient used to control invasive species in the United States.

Glyphosate is a versatile active ingredient and can be applied with many different types of application equipment depending on the needs of the user. In addition to the broadcast spray applications, it can be applied via application methods such as cut stump treatment, stem/tree injection, wick applications, spot treatment, and as a directed spray.

For more information on the benefits of glyphosate, see the *Glyphosate: Response to Comments, Usage, and Benefits*. In addition, the USDA provided non-agricultural usage information as a 2018 comment in the glyphosate public docket (EPA-HQ-OPP-2009-0361-1618), which furthered the agency's understanding of the benefits of glyphosate to this sector.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

The EPA did not identify any human health risks from exposure to glyphosate. The agency identified potential ecological risk to mammals and birds, but these risks are expected to be limited to the application area or areas near the application area. The EPA also identified potential risk to terrestrial and aquatic plants from off-site spray drift, consistent with glyphosate's use as an herbicide.

Glyphosate is a versatile herbicide that provides a broad spectrum of weed control across numerous agricultural and non-agricultural sites. Glyphosate is generally inexpensive in agricultural settings. Glyphosate is important in the management of invasive/noxious weeds and is a critical tool for habitat restoration efforts for rangeland and pastures. It is used for weed management for rights-of-way, forestry, industrial settings, residential areas, and aquatic environments.

The EPA concludes that the benefits outweigh the potential ecological risks when glyphosate is used according to label directions. To reduce off-site spray drift to non-target organisms, the agency is requiring spray drift management labeling. Since the PID was issued and in response to comments, the agency has made changes to the spray drift management language relating to droplet size, updated the swath displacement language based on current EPA policy, and removed the proposed advisory spray drift language for application via airblast, as airblast is not an application method used for glyphosate. In addition, EPA has adjusted the required language for rotational crop timing information based on the comments received. All required mitigation measures are detailed in Appendices A and B.

1. Spray Drift Management

The agency is requiring label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all glyphosate products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of glyphosate.

The agency is requiring the following spray drift mitigation language to be included on all glyphosate product labels for products applied by liquid spray application. The required spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The agency is providing recommendations which allow glyphosate registrants to standardize all advisory language on glyphosate product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements required in this ID once added to the labels.

- Applicators must not spray during temperature inversions.

- For aerial applications, do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor blade diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the ground or crop canopy, unless a greater application height is required for pilot safety.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground and/or aerial applications, select nozzle and pressure that deliver Medium or coarser droplets as indicated in nozzle manufacturer's catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE S572.1), unless tank-mixing with a pesticide product that requires use of a finer droplet size (ASABE S572.1). If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1).

The agency's goal is to manage off-target spray drift from applications of glyphosate while continuing to preserve glyphosate's utility for growers and allow growers continued flexibility when making applications. The agency assessed the potential impact on growers of the required spray drift management restrictions and has determined that these measures are not expected to substantially reduce the benefits of glyphosate to users. Prohibiting glyphosate applications during temperature inversions may impact the usability of glyphosate products by reducing the amount of time users have to apply glyphosate, but growers can switch to other products if they encounter temperature inversions.

For the PID, the EPA considered the impact of requiring "fine" or coarser droplets (*i.e.*, requiring growers to deliver droplets no smaller than "fine") on glyphosate labels and determined that such a requirement was not likely to affect the efficacy of glyphosate when used alone since it is a systemic herbicide. The agency is now requiring "medium" or coarser droplet size where glyphosate is the sole active ingredient being applied in order to further reduce drift. Efficacy is anticipated to be unaffected based on comments received from the public. Glyphosate is a compound that is frequently tank-mixed with other herbicides. Given that the language provides flexibility with droplet size for tank-mixed partners, the EPA does not expect there would be concerns for tank mixing with other herbicides. However, since glyphosate can be applied as a burndown treatment, insecticides may be included in the tank mix. Insecticides are generally considered to provide better efficacy with smaller droplets, therefore EPA is allowing "fine" droplets for use in tank mixes with active ingredients that require "fine" or coarser droplets. The EPA is uncertain if requiring "fine" droplets will impact the efficacy of insecticides tank-mixed with glyphosate because some insecticides could be more effective at droplet sizes smaller than "fine" (such as "very fine" or "extremely fine"). If reduced efficacy occurred, the agency would expect growers to respond by increasing the application rates (if allowed by the label), increasing

the number of applications, increasing the application rates of tank-mix partners, making additional applications, or switching to a different active ingredient.

In addition to including the spray drift restrictions on glyphosate labels, all references to volumetric mean diameter (VMD) information for spray droplets are required to be removed from all glyphosate labels where such information currently appears. The new language above, which cites ASABE S572.1, eliminates the need for VMD information.

2. Herbicide Resistance Management

On August 24, 2017, the EPA finalized a Pesticide Registration Notice (PRN or Notice) on herbicide resistance management.[4] Consistent with the Notice, the EPA is requiring the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide PID and ID.

The development and spread of herbicide-resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. While herbicide-resistant weeds have been known since the 1950s, the number of species and their geographical extent has been increasing rapidly. Currently there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide-resistant weeds, both in controlling established herbicide-resistant weeds and in slowing or preventing the development of new herbicide-resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

The EPA is requiring measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

3. Non-target Organism Advisory

The protection of pollinators and other non-target organisms is a priority for the agency. While the agency did not identify risks to individual bees from glyphosate applications at rates below 5.7 lb ae/A, risks to terrestrial invertebrates at higher application rates are uncertain. In addition, glyphosate may impact non-target plants via spray drift and impact nectar sources and habitat for pollinators and other non-target organisms. EPA is requiring a non-target organism advisory to alert users of potential impact to non-target organisms: "This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas

[4] PRN 2017-2, "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship"

adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."

4. Label Consistency Measures

There are currently 557 Section 3 registrations and 37 Section 24(c) registrations for glyphosate. Label directions for glyphosate vary significantly from label to label, and newer stamped labels in general have more comprehensive instructions than older labels. The EPA is requiring all glyphosate labels to be updated to modern standards. The specific components of the label that require updates are as follows: the maximum application parameters, the environmental hazards statement for aquatic use, and clarification on rotational crop timing. In addition, the agency is providing guidance to glyphosate registrants on acceptable marketing statements.

Maximum Application Parameters

In 2013, at the agency's request and in preparation for risk assessment, the Joint Glyphosate Task Force, a consortium of glyphosate registrants, created a *Use Summary Matrix*, which was intended to summarize all use sites being supported as part of registration review and outline important application parameters such as maximum single and yearly application rates. EPA's risk assessments for glyphosate were based on maximum application parameters as described in the *Use Summary Matrix*. The maximum application rates on glyphosate labels must be consistent with the maximum application rates that were assessed by the agency and supported by the Joint Glyphosate Task Force. These maximum application parameters are described in Appendix C of this document.

Many older glyphosate labels do not define any maximum application parameters. EPA is requiring that maximum application parameters be clearly defined on all glyphosate labels and must not exceed the maximum application parameters as described in Appendix C. It is not EPA's intention to change the current application rates on glyphosate labels, but the agency is requiring defined rate limits in order to establish better consistency and clarity on labels. Appendix C lists the maximum application parameters by use site for both aerial and ground application.

Statements for Aquatic Uses

The EPA is requiring updated environmental hazards statements for aquatic use products to be consistent with modern standards and to be in line with newer pesticide labels. The glyphosate Reregistration Eligibility Decision (RED) issued in 1993 specified that glyphosate labels formulated for aquatic use have language intended to warn users of potential fish suffocation from aquatic applications. The EPA is requiring updates to the existing language to be consistent with current labeling guidance (see the EPA's Label Review Manual, and Table 4 below).

An additional statement under "directions for use" for aquatic use labels is required to instruct users to apply in strips to help avoid oxygen depletion when emerged weed infestations cover the total surface area of an impounded water body (see Table 4 below).

Table 4. Statements Required for Glyphosate for Aquatic Use

Product Type	Statement
Environmental hazards: for labels with terrestrial uses only	"Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Environmental hazards: for labels with aquatic uses only	"Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Environmental hazards: for labels with both aquatic and terrestrial uses	"Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark [*Optional text, if applicable*: except when applying this product by air over the forest canopy]. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."
Directions for use for aquatic uses	"When emerged weed infestations cover the total surface area of an impounded waterbody, apply this product to the emerged vegetation in strips to help avoid oxygen depletion in the water due to decaying vegetation. Oxygen depletion in the water can result in increased fish mortality."

Clarification on Rotational Crop Timing

Many glyphosate labels lack instructions for crop rotation. The EPA is requiring the clarification that treated fields may be rotated to a labeled crop at any time. For fields being rotated to a non-labeled crop, any glyphosate application must be made a minimum of 30 days prior to planting. EPA is updating the language that was proposed in the PID to further clarify the instructions on rotational crop timing based on public comments received.

Label Claims

During meetings with the agency in 2018, the Joint Glyphosate Task Force proposed to clarify on existing labels a statement about how glyphosate works. The following statement is being required: "Glyphosate works by targeting an enzyme that is essential for plant growth." The revision is consistent with the requirements of 40 CFR § 156.10(a)(5). Registrants may use alternate claims, as long as alternate claims meet labeling requirements. Registrants can refer to 40 CFR § 156.10(a)(5) for requirements regarding label claims prior to submitting updated labels for registration review.

B. Tolerance Actions

The EPA is requiring the following revisions for glyphosate tolerances: adjusting the number of significant figures, establishing new tolerances for various vegetable and fruit groups/subgroups, and deleting certain older tolerances which are no longer needed due to the new tolerance

groupings. Refer to Section III.A.3 of this document for the required tolerance changes. The agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances. The agency intends to address the tolerance revisions requested by the EWG et al. petitioners in its response to their petition and has not addressed them in this document.

C. Interim Registration Review Decision

In accordance with 40 CFR § 155.56 and 155.58, the agency is issuing this Interim Registration Review Decision. Except for the EDSP, ESA, and resolution of the EWG et al. petition, the agency has made the following Interim Registration Review Decision: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed, as described in Section IV. A. and Appendices B and C. This document finalizes the agency's draft supporting documents: *Glyphosate Draft Human Health Risk Assessment for Registration Review*, and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts.*

In this interim registration review decision, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate, nor is it making a complete endangered species finding. This interim registration review decision does not address the specific claims raised in the EWG et al. petition, nor does it constitute EPA's response to the petition. Although the agency is not making a complete endangered species finding at this time, the mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of glyphosate. The agency's final registration review decision for glyphosate will be dependent upon the result of the agency's ESA assessment and any needed section 7 consultation with the Services, an EDSP FFDCA section 408(p) determination, and after a resolution of the EWG et al. petition.

D. Data Requirements

No additional data are required for this registration review at this time. The EPA will consider requiring the glyphosate registrants to submit pollinator data as a separate action.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this Interim Registration Review Decision for glyphosate. A final decision on the glyphosate registration review case will occur after: (1) an EDSP FFDCA §408(p) determination, (2) an endangered species determination under the ESA and any needed §7 consultation with the Services, and (3) a resolution of the EWG et al. petition. This document finalizes the agency's draft supporting documents: *Glyphosate Draft Human Health Risk Assessment for Registration Review*, and *Registration Review—Preliminary Ecological Risk Assessment for Glyphosate and Its Salts.*

B. Implementation of Mitigation Measures

Given the anticipated timeframe for the agency's response to the EWG et al. petition in 2020, labels should not be submitted at this time. Once the agency completes its response to the petition, it will issue letters to glyphosate registrants requesting label submission to incorporate the glyphosate required interim risk mitigation (see Appendices A, B, and C), which will be posted to the docket. Revised labels and requests for amendment of registrations will be required for submission to the agency for review within 60 days following the issuance of letters.

Appendix A: Summary of Required Actions for Glyphosate

Registration Review Case#: 0178
PC Codes: 103601, 103604, 103605, 103607, 103608, 103613, 417300
Chemical Type: herbicide
Chemical Family: glycine derivative
Mode of Action: targets the 5-enolpyruvyl-3-shikimate phosphate synthase enzyme

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions	Comment
Terrestrial and aquatic plants	Spray drift	Foliar absorption	Acute Chronic	Survival, biomass	Require enforceable spray drift management language; updated environmental hazards language	
Birds	Residues on food items (via deposition or spray drift)	Dietary	Acute Chronic	Growth	Require enforceable spray drift management language	Risks are likely limited to the field and areas near the application field.
Mammals	Residues on food items (via deposition or spray drift)	Dietary	Acute Chronic	Growth and reproduction	Require enforceable spray drift management language	Risks to are likely limited to the field and areas near the application field.
Terrestrial invertebrates	Residues on nectar sources (via deposition or spray drift)	Dietary	Acute Chronic	Effects on nectar sources of terrestrial invertebrates	Non-target organism environmental hazards language	Risks to bees are uncertain at application rates higher than 1.9 lb ae/A. The agency may require additional pollinator data to fully assess risk to terrestrial invertebrates.

Appendix B: Required Labeling Changes for Glyphosate Products

Description	Required Label Language for Glyphosate Products	Placement on Label
	End Use Products	
Mechanism of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP**" in the second column • Include the **MODE/MECHANISM OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide (*i.e.*, **HERBICIDE** or **FUNGICIDE** or **INSECTICIDE**) in the fourth column. **Glyphosate** | **GROUP** | **9** | **HERBICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Non-target Organism Advisory	"NON-TARGET ORGANISM ADVISORY: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."	Environmental Hazards
Environmental Hazards Statement for Aquatic Use	*For labels without aquatic uses:* "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate." *For labels with aquatic uses only:* "Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate." *For labels with both aquatic and terrestrial uses:* "Killing aquatic weeds can result in depletion or loss of oxygen in the water due to decomposition of dead plant material. This oxygen loss can cause fish suffocation. Consult with your	Environmental Hazards

Description	Required Label Language for Glyphosate Products	Placement on Label
	State agency with primary responsibility for regulating pesticides before applying to public waters to determine if a permit is required. For terrestrial uses, do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high-water mark [*Optional text, if applicable*: except when applying this product by air over the forest canopy]. Do not contaminate water when cleaning equipment or disposing of equipment wash waters and rinsate."	
Aquatic Use Statement	"When emerged weed infestations cover the total surface area of an impounded waterbody, apply this product to the emerged vegetation in strips to help avoid oxygen depletion in the water due to decaying vegetation. Oxygen depletion in the water can result in increased fish mortality."	Directions for Use
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action (Applies to all products delivered via liquid spray applications)	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Rotational crop information	"This product may be applied during fallow intervals preceding planting, prior to planting or transplanting, at-planting, or preemergence to annual and perennial crops listed on this label, except where specifically limited. For any crop not listed on this label, application must be made a minimum of 30 days prior to planting."	Directions for Use
Label claims	"Glyphosate works by targeting an enzyme that is essential for plant growth." [Alternate claims, if used, must meet labeling requirements. Refer to 40 CFR § 156.10(a)(5) for requirements regarding label claims.]	Product Information
Clarification of application rates	Ground and aerial applications rates on the labels must not exceed the maximum application parameters as noted in Appendix C of this document, which were maximum application parameters assessed by the EPA. Application rates may only be clarified for uses that are currently approved on labels.	Directions for Use

Description	Required Label Language for Glyphosate Products	Placement on Label
Spray Drift Management Application Restrictions for all products that are delivered via liquid spray applications and allow aerial application	**"MANDATORY SPRAY DRIFT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) unless tank-mixing with a pesticide product that requires use of a finer droplet size. If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1). • If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply when wind speeds exceed 15 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Aerial Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and allow ground boom applications	**"MANDATORY SPRAY DRIFT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) unless tank-mixing with a pesticide product that requires use of a finer droplet size. If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are delivered via liquid spray applications and allow boomless ground sprayer applications	**"MANDATORY SPRAY DRIFT** **Boomless Ground Applications:** • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1) unless tank-mixing with a pesticide product that requires use of a finer droplet size. If a finer droplet size is used, applicators are required to use a Fine or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 15 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift" under the heading "Boomless Applications"

Description	Required Label Language for Glyphosate Products	Placement on Label
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Required Label Language for Glyphosate Products	Placement on Label
	Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which can cause small droplets to remain suspended in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They can begin to form in late afternoon/early evening and often continue into the morning. Their presence can be indicated by ground fog. If fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for products that are delivered via liquid spray applications and allow boomless ground sprayer applications	"**SPRAY DRIFT ADVISORIES** **Boomless Ground Applications:** • Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	"**SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Appendix C: Maximum Application Rates for Glyphosate Ground and Aerial Application[5]

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Round-up Ready 2 Yield Soybeans	3.75	1.55	6
Root Tuber Vegetables: arracacha, arrowroot, carrot, chinese artichoke, Jerusalem artichoke, beet (garden), burdock, canna, cassava (bitter and sweet), celeriac, chayote (root), chervil (turnip-rooted), chicory, chufa, dasheen (taro), galangal, ginger, ginseng, horseradish, leren, kava (turn-rooted), parsley (turnip-rooted), parsnip, potato, radish, rutabaga, oriental radish, salsify, skirret, sweet potato, tanier, turmeric, turnip, wasabi, yacon, yam bean, true yam	3.75	1.55	6
Rangelands	0.38	0.38	2.25
Pome Fruits: including apple, crabapple, loquat, mayhaw, pear, oriental pear, quince	3.75	1.55	8
Pastures	8	8	8
Oilseed Crops: borage, buffalo gourd, calendula, canola, castor oil plant, chinese tallow tree, crambe, cuphea, echium, euphorbia, evening primrose, flax (seed), gold of pleasure, hare's ear mustard, jojoba, lesquerella, meadow foam, milkweed, mustard (seed), niger (seed), oil radish, poppy seed, rapeseed, rose hip, safflower, sesame, stokes aster, sunflower, sweet rocket, tallow wood, tea oil plant, veronia.	3.75	1.55	6
Non-Food Tree Crops: pine, poplar, eucalyptus, christmas trees, other non-food tree crops	8	8	8
Miscellaneous Tree Food Crops: cactus (fruit and pads), palm (heart, leaves, oil)	3.75	1.55	8
Miscellaneous Crops: aloe vera, bamboo shoots, globe artichoke, okra, peanut (ground nut), strawberry, sugar beet, asparagus, pineapple	3.75	1.55	6
Legume Vegetables: Succulent varieties of Bean (Lupinus: includes grain lupin, sweet lupin, white lupin, white sweet lupin); Bean (Phaseolus: includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean, wax bean); Bean (Vigna: includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); Broad bean (fava); Chickpea (garbanzo); Guar; Jackbean; Lablab bean; Lentil; Pea (Pisum: includes dwarf pea, edible-podded pea, English pea, field pea, garden pea, green pea, snowpea, sugar snap pea); Pigeon pea; Soybean (immature seed); Sword bean. Dry varieties of Bean (Lupinus: includes grain lupin, sweet lupin, white lupin, white sweet lupin); Bean (Phaseolus: includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean,	3.75	1.55	6

[5] It is not EPA's intention to change the current application rates on glyphosate labels, but the agency is requiring defined rate limits on labels in order to establish better consistency and clarity on labels.

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
tepary bean, wax bean); Bean (Vigna: includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, yardlong bean); Broad bean (fava); Chickpea (garbanzo); Guar; Jackbean; Lablab bean; Soybean (immature seed); Sword bean Dry varieties of Lentil; Pea (Pisum: includes dwarf pea, edible-podded pea, English pea, garden pea, green pea, snowpea, sugar snap pea); Pigeon pea			
Leafy Vegetables: Amaranth (Chinese spinach); Arugula (roquette); Beet greens; Cardoon; Celery; Chinese celery; Celtuce; Chaya; Chervil; Edible-leaved chrysanthemum; Garland chrysanthemum; Corn salad; Cress (garden and upland); Dandelion; Dock (sorrel); Dokudami; Endive (escarole); Florence fennel; Gow kee; Lettuce (head and leaf); Orach, Parsley; Purslane (garden and winter); Radicchio (red chicory); Rhubarb; Spinach; New Zealand spinach; Vine spinach; Swiss chard; Watercress (upland); Water spinach	3.75	1.55	6
Herbs and Spices: Allspice, Angelica, Star anise, Annatto (seed), Balm, Basil, Corage, Burnet, camomile, Caper buds, Caraway, Black caraway, Cardamom, Cassia bark, Cassia buds, Catnip, Celery seed, Chervil (dried), Chive, Chinese chive, Cilantro (leaf), Cilantro (seed), Cinnamon, Clary, Clove buds, Coriander leaf (cilantro or Chinese parsley), Coriander seed (cilantro), Costmary, Cumin, Curry (leaf), Dill (dillweed), Dill (seed), Epazote, Fennel seed (common and Florence), Fenugreek, White ginger flower, Grains of paradise, Horehound, Hyssop, Juniper berry, Lavender, Lemongrass, Lovage (leaf and seed), Mace, Marigold, Marjoram (including oregano), Mexican oregano, Mioga flower, Mustard (seed), Nasturtium, Nutmeg, Parsley (dried), Pennyroyal, Pepper (black and white), Pepper leaves, Peppermint, Perilla, Poppy (seed), Rosemary, Rue, Saffron, Sage, Savory (summer and winter), Spearmint, Stevia levaes, Sweet bay, Tansy, Tarragon, Thyme, Vanilla, Wintergreen, Woodruff, Wormwood	3.75	1.55	6
Grass/Turfgrass/Sod Production	3.75	1.55	6
Grain Sorghum	3.75	1.55	6
Fruiting Vegetables: Eggplant; Groundcherry (Physalis spp); Pepino; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Tomato	3.75	1.55	6
Forestry	8	8	8
Fallow	3.75	1.55	6
Cucurbits Vegetables/Fruit: Chayote (fruit); Chinese waxgourd (Chinese preserving melon); Citron melon; Cucumber; Gherkin; Edible gourd (includes hyotan, cucuzza, hechima, Chinese okra); Melons (all); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); Muskmelon (includes cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey ball melon, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake melon); Pumpkin; Summer squash	3.75	1.55	6

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
(includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); Winter squash (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); Watermelon			
Cotton	3.75	1.55	6
Corn (Field, Seed, Silage, Popcorn)	3.75	1.55	6
Conservation Reserve Program	3.75	1.55	6
Citrus Fruit Crop: All cultivars, varieties and/or hybrids of Calamondin; Chironja; Citron; Citrus hybrids; Grapefruit (including Japanese summer); Kumquat; Lemon; Lime (including Australian desert lime, Australian finger lime, Australian round lime, Brown river finger lime, Mount white, New Guinea wild, Russell river, sweet, and Tahiti); Mandarin (including Mediterranean and Satsuma); Orange (all); Pummelo; Tangelo; Tangerine (Mandarin); Tangor; Uniq Fruit (ugli)	3.75	1.55	8
Cereal and Grain Crop: barley, buckwheat, millet, oats, rye, quinoa, teff, teosinte, triticale, wild rice, rice, feed barley, wheat	3.75	1.55	6
Bulb Vegetables: All cultivars, varieties and/or hybrids of Chive (fresh leaves, including Chinese chive); Daylily (bulb); Elegans hosta; Fritillaria (bulb and leaves); Garlic (bulb, including great-headed and serpent garlic); Kurrant, Leek (including lady's and wild leek); Lily (bulb); Onion (including Beltsville bunching, bulb, Chinese bulb, fresh, green, macrostem, pearl, potato bulb, tree tops and Welsh onion tops); Shallot (bulb and fresh leaves)	3.75	1.55	6
Brassica Vegetable: Broccoli; Chinese broccoli (gai lon); Broccoli raab (rapini); Brussels sprouts; Cabbage; Chinese cabbage (bok choy); Chinese cabbage (napa); Chinese mustard cabbage (gai choy); Cauliflower; Cavalo broccoli; Collards; Kale; Kohlrabi; Mizuna; Mustard greens; Mustard spinach; Rape greens	3.75	1.55	6
Round-up Ready Flex Cotton	3.75	1.55	6
Round-up Ready Cotton	3.75	1.55	6
Round-up Ready Corn (GA-21)	3.75	1.55	6
Round-up Ready Corn 2 (NK603)	3.75	1.55	6
Round-up Ready Alfalfa	1.55	1.55	6
Round-up Ready Sugarbeets	3.75	1.55	6
Tropical/Subtropical Trees/Fruits: Ambarella; Atemoya; Avocado; Banana; Barbados cherry (acerola); Biriba; Blimbe; Breadfruit; Cacao (cocoa) bean; Canistel; Carambola (starfruit); Cherimoya; Coffee; Custard apple; Dates; Durian; Feijoa; Figs; Governor's plum; Guava; Ilama; Imbe; Imbu; Jaboticaba; Jackfruit; Longan; Lychee; Mamey apple; Mango; Mangosteen; Marmaladebox (genip); Mountain papaya; Noni	3.75	1.55	8

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
(Indian mulberry); Papaya; Pawpaw; Plantain; Persimmon; Pomegranate; Pulasan; Rambuttan; Rose apple; Sapodilla; Sapote (black, mamey, white); Spanish lime; Soursop; Star apple; Sugar apple; Surinam cherry; Tamarind; Tea; Ti (roots and leaves); Wax jambu			
Tree Nut Crops: Cultivars, varieties, and/or hybrids of African nut-tree; Almond; Beechnut; Brazil nut; Brazilian pine; Bunya; Burr oak; Butternut; Cajou nut; Candlenut; Cashew; Chestnut; Chinquapin; Coconut; Coquito nut; Dika nut; Ginkgo; Guiana chestnut; Hazelnut (Filbert); Heartnut; Hickory nut; Japanese horse-chestnut; Macadamia nut; Mongongo nut; Monkey-pot; Monkey puzzle nut; Okari nut; Pachira nut; Peach palm nut; Pecan; Pequi; Pili nut; Pine nut; Pistachio; Sapucaia nut; Tropical almond; Walnut (black, English); Yellowhorn	3.75	1.55	8
Sweet Corn	3.75	1.55	6
Sugar Cane	3.75	2.25	6
Stone Fruit: All cultivars, varieties and/or hybrids of Apricot; Cherry (sweet and tart); Nectarine; Olive; Peach; Plum/Prune (all types); Plumcot	3.75	1.55	8
Round-Up Ready Canola (Winter Varieties)	1.55	1.55	6
Soybeans	3.75	1.55	6
Sweet Corn with Round-Up Ready 2 Technology	3.75	1.55	6
Round-Up Ready Canola (Spring Varieties)	1.55	1.55	6
Vine Crops: grapes (raisin, table, wine), hops, passion fruit, kiwi	3.75	1.55	8

Crop Group	Ground Maximum Single Application Rate (lb a.e./A)	Aerial Maximum single application rate (lb a.e./A)	Maximum Annual Application Rate (lb a.e./A)
Non-Crop: Airports, airfields, apartment complexes, commercial sites, ditch banks, driveways, ramps, alleys, lanes, paths, trails, sidewalks, walkways, access roads, farm roads, highways (including aprons, medians, guardrails, and rights-of-way), paved areas and prior to paving, dry ditches, dry canals, fences and fencerows, golf courses, greenhouses, industrial sites, landscape areas, lumber yards, manufacturing sites, municipal sites, natural areas, office complexes, ornamentals, parks, campgrounds, sports areas, tennis courts, parking areas, cemeteries, petroleum or other tank farms and pumping installations, refineries, around telephone and communications equipment, public areas, drive-in theaters, railroads (including ballasts, shoulders, crossings and spot treatments), recreation areas, residential areas, rights-of-way, roadsides, firebreaks, schools, shadehouses, sports complexes, storage areas, substations, construction and pre-construction sites, turfgrass areas, around ornamental gardens, around ornamental trees and shrubs, power and utility sites, around commercial or industrial outbuildings, warehouse areas, bare ground, gravel yards, mulched areas, beaches, habitat restoration and management areas, uncropped farmstead areas, uncultivated non-agricultural areas, vacant lots, wastelands, shelter belts, and wildlife management areas. Natural Woodlands, including Wildlife and Habitat Management Areas, Wildlife Openings, Natural Areas (such as Wildlands and Wildlife Refuge), Campgrounds, Parks and Recreational Areas in Natural Forests, and Reforestation Treatments in Natural Forests	8	8	8
Aquatic	8	8	8
Alfalfa, Clover, and Other Forage Legumes, including: kudzu, lespedeza, lupin, sainfoin, trefoil, velvet bean, vetch, kenaf, leucaena	3.75	1.55	6
Berry and Small Fruit Crops: All cultivars, varieties and/or hybrids of Amur River grape; Aronia berry; Bayberry; Bearberry; Bilberry; Blackberry (including Andean blackberry, arctic blackberry, bingleberry, black satin berry, boysenberry, brombeere, California blackberry, Chesterberry, Cherokee blackberry, Cheyenne blackberry, common blackberry, coryberry, darrowberry, dewberry, Dirksen thornless berry, evergreen blackberry, Himalayaberry, hullberry, lavacaberry, loganberry, lowberry, Lucretiaberry, mammoth blackberry, marionberry, mora, mures deronce, nectarberry, Northern dewberry, olallieberry, Orgeon evergreen berry, phenomenalberry, rangeberry, ravenberry, rossberry, Shawnee blackberry, Southern dewberry, tayberry, youngberry, zarzamora); Blueberry (highbush and lowbush); Buffaloberry; Che; Chilean guava; Chokecherry; Cloudberry; Cranberry (including highbush); Currant (black, Buffalo, red, native); Elderberry; European barberry; Gooseberry; Grape; Honeysuckle (edible); Huckleberry; Jostaberry; Juneberry (Saskatoon berry); Kiwifruit (fuzzy and hardy); Ligonberry; Maypop; Mountain pepper berries; Mulberry; Muntries; Partridgeberry; Phalsa; Pincherry; Raspberry (black, red and wild); Riberry; Salal; Schisandra berry; Sea buckthorn; Serviceberry	3.75	1.55	8

Appendix D: Endangered Species Assessment

This Appendix provides general background about the Agency's assessment of risks from pesticides to endangered and threatened (listed) species under the Endangered Species Act. Additional background specific to glyphosate appears at the conclusion of this Appendix.

In 2013, the EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides[6]. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations. These initial consultations were pilots and were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, advancements to the initial pilot interim methods have been proposed based on experience conducting the first three pilot BEs. Public input on those proposed revisions is currently being considered.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role on this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this ID for glyphosate does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although the EPA has not yet completed effects determinations for specific species or habitats, for this ID, the EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of glyphosate. This will allow the EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for glyphosate as part of completing this registration review.

[6] https://www.epa.gov/endangered-species/draft-revised-method-national-level-endangered-species-risk-assessment-process

Glyphosate is one of the chemicals in stipulated partial settlement agreement in the case of Center for Biological Diversity et al., v. United States Environmental Protection Agency et al., No. 3:11 cv 0293 (N.D. Cal.). Among other provisions, this agreement sets an August 14, 2021, deadline for EPA to complete nationwide ESA section 7(a)(2) effects determination for glyphosate and, as appropriate, request initiation of any ESA section 7(a)(2) consultations with the Services that EPA may determine to be necessary as a result of those effects determinations.

Appendix E: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for glyphosate, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), glyphosate is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. Glyphosate is on List 1 and the review conclusions are available in the glyphosate public docket (see EPA-HQ-OPP-2009-0361). A second list of chemicals identified for EDSP screening was published on June 14, 2013,[7] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[8]

[7] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[8] https://www.epa.gov/endocrine-disruption

In this ID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of glyphosate. Before completing this registration review, the agency will make an EDSP FFDCA § 408(p) determination.